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ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,021	MICHNICK ET AL.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 and 31-39 is/are rejected.

7)☒ Claim(s) 16,30 and 35 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 05 February 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/017,412.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

First set of species: species of molecule fused to reporter fragments as listed in claims 36 and 37. Each species of polypeptide sequence listed in claims 36 and 36 have a different structure and have a different biological function. Due to these differences, the search for each species is different.

Second set of species: species of cellular pathway analyzed by the method, as listed in claim 38. Each species of cellular pathway involves a different series of biological reactions that involves different biological molecules with different structures and functions. Due to these differences, the search for each cellular pathway is different.

Third set of species: species of drug category assayed by the method, as listed in claim 39. Each species of drug category has constituents with different structures and biological functions. Due to these differences, the search for each cellular pathway is different.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for set 1, claims 1-35, 38, and 39 are generic, for the second set claims 1-37 and 39 are generic, and for the third set claims 1-38 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Isaac Angres on 14 October 2004 a provisional election was made with traverse to prosecute the invention of species p53 fused to reporter fragment, claims 36 and 37, species receptor tyrosine kinase cellular pathway, claim 38, and receptor agonist drug category, claim 39. Affirmation of this election must be made by applicant in replying to this Office action.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Regarding species of molecule fused to a reporter fragment, generic claim 26 is rejected and the elected species p53 of claims 35 and 36 is also rejected.

5. Regarding species of cellular pathway, generic claim 2 is rejected and the elected tyrosine kinase receptor species of claim 38 is also rejected.

6. Regarding species of drug category, generic claim 26 is rejected and claim 39 is also rejected.

Specification

7. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Claim Objections

8. Claims 16 and 35 are objected to because of the following informalities: In claim 16, the term "Claims" appears in line one and should be replaced with "claim.". In claim 35 the phrase "any one of" in line one should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 6, 9, 19, 20, and 31-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6, 9, 19, 20, and 35 are drawn to methods and compositions comprising a phosphorescent reporter protein fragment. The specification describes a variety of reporter protein fragments on pages 4-6 and Table 1 on pages 14-16. The specification does not describe phosphorescent proteins or phosphorescent reporter protein fragments.

Claim 31 is drawn to fusion proteins comprising multiple fragments of a reporter molecule. The specification describes in figures 16 and 17 fusion proteins with one fragment of a reporter protein. The specification does not describe fusion proteins with a plurality of fragments of a reporter protein.

Claims 32-34 are drawn to expression vectors that comprise reporter fragments. The specification describes expression vectors on pages 62-64 that comprise polynucleotides that encode reporter fragments. The specification does not describe expression vectors that comprise reporter fragments.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 13 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 13 recites the limitation "the molecules fused to the reporter fragments of the PCA" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 31 is indefinite because it recites the phrase "the fragment" in lines 7 and 11 and it is not clear which of the plurality of fragments the phrase refers to.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 26-29, and 39 are rejected under 35 U.S.C. 102b as being anticipated by Johnsson et al.

The claims are drawn to fusion proteins comprising fragments of reporter molecules that have a detectable activity when associated. It is noted that limitations regarding intended use of the compositions in claim 26 have not been given patentable weight because the limitations do not limit the structure of the claimed compositions.

Johnsson shows an assay of fusion protein reassociation in figure 1e. The assay utilizes fragments of ubiquitin that do not reassociate unless linked to protein domains that have high binding affinity. Upon binding, the ubiquitin fragments are brought into close association and cleave a portion of one of the ubiquitin fragments. The cleavage activity is measured by gel electrophoresis immunoblot analysis in figure 4.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 26, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnsson et al. in view of Ko et al.

The claims are drawn to fusion proteins comprising fragments of reporter molecules that have a detectable activity when associated. At least one of the fusion proteins comprises p53. It is noted that limitations regarding intended use of the compositions in claim 26 have not been given patentable weight because the limitations do not limit the structure of the claimed compositions.

Johnsson shows an assay of fusion protein reassociation in figure 1e. The assay utilizes fragments of ubiquitin that do not reassociate unless linked to protein domains that have high

binding affinity. Upon binding, the ubiquitin fragments are brought into close association and cleave a portion of one of the ubiquitin fragments. The cleavage activity is measured by gel electrophoresis immunoblot analysis in figure 4. Johnsson et al. does not show a fusion protein comprising p53.

Ko et al. reviews the biology of p53. Ko et al. shows that p53 is a tumor suppressor gene that binds many cellular components, detailed in figure 1 and Table 1. Ko et al. review multiple cellular pathways that p53 appears to play a role in, including apoptosis and cell cycle arrest, differentiation, and DNA repair and replication.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the fusion proteins of Johnsson et al. by use of a fusion protein that comprises p53 because Ko et al. shows that p53 is an important protein involved in tumor suppression that plays a role in multiple cellular pathways and that binds multiple proteins and because use of the protein association assay of Johnsson et al. would allow for interactions of p53 with other proteins to be assayed to allow for further insights into the functions of p53.

Double Patenting

21. Applicant is advised that should claim 27 be found allowable, claim 28 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

24. Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

25. Claims 1-6, 8-12, 14-29, and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, and 11-14 of copending Application No. 10/856620. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending claim 5 is a species of the instant claimed method and copending Application No. 10/856620 discloses fluorescent reporter proteins on page 10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-6, 8-12, 14-29, and 35 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by copending Application No. 10/856620, which has a different inventive entity than the instant application.

27. Claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 13, 14, and 16 of copending Application No. 10/724178 Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are species of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by copending Application No. 10/724178, which has a different inventive entity than the instant application.

29. Claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 74, 77, 80, and 82 of copending Application No. 10/353090 Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are species of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

30. Claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by copending Application No. 10/353090, which has a different inventive entity than the instant application.

31. Claims 5-9, 11, 15, 17-20, 22, and 24-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 59-70, and 73-80 of copending Application No. 10/154758. Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the copending claims are species of the instant claims and the copending application discloses fluorescent reporter proteins on page 38.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

32. Claims 5-9, 11, 15, 17-20, 22, and 24-29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by copending Application No. 10/154758, which has a different inventive entity than the instant application.

33. Claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 18, 19, and 20-33 of copending Application No. 09/603885. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are species of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

34. Claims 5-9, 11, 15, 17, 19, 20, 22, and 24-29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by copending Application No. 09/603885, which has a different inventive entity than the instant application.

35. Claims 5-9, 11, 15, 17-20, 22, and 24-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-16, and 18 of U.S. Patent No. 6,428,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the issued claims are species of the instant claims and the issued patent discloses fluorescent reporter proteins in columns 23-24.

36. Claims 5-9, 11, 15, 17-20, 22, and 24-29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by U.S. Patent No. 6,428,951, which has a different inventive entity than the instant application.

37. Claims 1-9, 11, 14, 15, 17-20, 22, and 24-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent No. 6,294,330. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are species of the instant claims.

38. Claims 1-9, 11, 14, 15, 17-20, 22, and 24-29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by U.S. Patent No. 6,294,330, which has a different inventive entity than the instant application.

39. Claims 1-9, 11, 15, 17-20, 22, and 24-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,270,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued patent claims species of the instant claims.

40. Claims 1-9, 11, 15, 17-20, 22, and 24-29 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As discussed above, the instant claims are anticipated by U.S. Patent No. 6,270,964, which has a different inventive entity than the instant application.

41. Claims 2 and 38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of copending Application No. 10/856620 in view of Panayotou et al.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 2-5 of Application No. 10/856620 are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a cellular protein. Claims 2-5 of Application No. 10/856620 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after

activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 2-5 of Application No. 10/856620 by use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

This is a provisional obviousness-type double patenting rejection.

42. Claims 2 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over copending Application No. 10/856620 (which qualifies as prior art under 35 U.S.C. § 102(f)) in view of Panayotou.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 2-5 of Application No. 10/856620 are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a cellular protein. Claims 2-5 of Application No. 10/856620 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 2-5 of Application No. 10/856620 by use of a

receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

43. Claims 2 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 in view of Panayotou et al.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a cellular receptor protein. Claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 by use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

44. Claims 2 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,294,330 (which qualifies as prior art under 35 U.S.C. § 102(f)) in view of Panayotou.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a cellular receptor protein. Claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 3, 4, and 13-22 of U.S. Patent No. 6,294,330 by use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

45. Claims 2 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27 and 37 of U.S. Patent No. 6,270,964 in view of Panayotou et al.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 27 and 37 of U.S. Patent No. 6,270,964 are drawn to a method of using a protein complementation assay to study the effect of a compound on a cellular protein. Claims 27 and 37

of U.S. Patent No. 6,270,964 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 27 and 37 of U.S. Patent No. 6,270,964 by use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

46. Claims 2 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,270,964 (which qualifies as prior art under 35 U.S.C. § 102(f)) in view of Panayotou.

The claims are drawn to a method of using a protein complementation assay to study the effect of a chemical compound on a receptor tyrosine kinase pathway.

Claims 27 and 37 of U.S. Patent No. 6,270,964 are drawn to a method of using a protein complementation assay to study the effect of a compound on a cellular protein. Claims 27 and 37 of U.S. Patent No. 6,270,964 do not show use of protein complementation assays to study a receptor tyrosine kinase pathway.

Panayotou et al. reviews receptor tyrosine kinases. Panayotou et al. shows on pages 172-174 and figure 2 that many receptor tyrosine kinases bind a variety of cellular proteins after

activation of the receptor tyrosine kinase, and that such binding is essential for effecting the cell signal of extracellular ligand binding to the receptor.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the assays of claims 27 and 37 of U.S. Patent No. 6,270,964 by use of a receptor tyrosine kinase protein linked to a reporter molecule because such a fusion protein would allow for further study of binding to the receptor tyrosine kinase by other proteins.

Allowable Subject Matter

47. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

48. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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J.S. Brusca 28 October 2004

John S. Brusca
Primary Examiner
Art Unit 1631

jsb